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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/559,013	04/26/2000	Toshiro Ono	L0461/7086(JRV)	1882

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EXAMINER

CANELLA, KAREN A

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 01/29/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

69/559,013

Applicant(s)

Ono et al

Examiner

KAREN CANELLA

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 30 days MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

68, 69, 71, 72, 75, 76, 79, 86, 90, 97, 101, 105, 108, 113, 119

- 4) ☒ Claim(s) 1, 2, 6, 15, 19, 36, 38, 41, 47, 53, 54, 56, 60, 62-64, 66 is/are pending in the application.

4a) Of the above, claim(s) 36, 38 is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1, 2, 6, 15, 19, 41, 47, 53, 54, 56, 60, 62-64 are subject to restriction and/or election requirement.
66, 68, 69, 71, 72, 75, 76, 79, 86, 90, 97, 101, 105, 108, 113, 119

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other: _____

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DETAILED ACTION

1. Claims 3-5, 7-14, 16-18, 20-35, 37, 39, 40, 42-46, 48-52, 55, 57-59, 61, 65, 67, 70, 73, 74, 77, 73, 74, 77, 78, 80-85, 87-89, 91-96, 98-100, 102-104, 106, 107, 109-112, 114-118, 120 and 121 have been canceled. Claims 36, 38, 47, 53, 60, 68, 101 and 113 have been amended. Claims 1, 2, 6, 15, 19, 36, 38, 41, 47, 53, 54, 56, 60, 62-64, 66, 68, 69, 71, 72, 75, 76, 79, 86, 90, 97, 101, 105, 108, 113 and 119 are pending. Claims 36 and 38, dependent upon canceled claims, are withdrawn from consideration.

Election/Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
- I. Claim 1, in part, and claim 2 (a-c) drawn to methods of diagnosing a disorder comprising contacting a sample with nucleic acids, classified in class 435, subclass 6. Claim 1 will be examined with this group to the extent that it reads on the detection of nucleic acids.
 - II. Claim 1, in part, claim 2(d-I), claim 6(I and ii) and claim 97, in part, drawn to methods of diagnosing a disorder comprising contacting a sample with an antibody which binds to NA expression products, or an agent which binds to a complex of an NA expression product and a MHC molecule, classified in class 435, subclass 7.23 Claim 1 will be examined to the extent that it reads on the detection of polypeptides. Claim 97 will be examined with this group to the extent that it reads on a method of diagnosis in contrast to a method of treatment.
 - III. Claim 6(iv) drawn to a method of diagnosing a disorder comprising detection of CTL specific for NA expression products and a MHC molecule, classified in class 435, subclass 7.24.
 - IV. Claim 6(iii) drawn to methods of diagnosing a disorder comprising the detection of antibodies which bind to NA expression products, classified in class 435, subclass 7.1.

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- V. Claims 79 and 101, drawn to methods of treatment comprising the administration of an agent which enriches selectively the presence of complexes of MHC molecules and a cancer associated antigen, wherein said agent is not an antibody or cell, classified, for example, in class 514, subclasses 14 and 44.
- VI. Claims, 86, 90 and 105 drawn to methods of treatment comprising the administration of a cell comprising NA expression products, classified in class 424, subclass 93.21.
- VII. Claim 108 and claim 97, in part, drawn to methods of treatment comprising the administration of an agent which inhibits the expression or activity of a protein encoded by NA Group I nucleic acid and methods of treatment comprising administering an antibody which binds to the expression product of NA Group I molecules, said antibodies coupled to a therapeutically useful agent, classified, for example, in class 530, subclass 391.7. Claim 97 will be examined with this group to the extent that it reads on a method of treatment.
- VIII. Claim 15 in part, claim 19 (part 2 and part 3) and claims 41, 54, 56, 60, 62, 63, 64, 66 and 76, drawn to isolated nucleic acids, kits comprising nucleic acids, pharmaceutical compositions comprising nucleic acids, expression vectors, host cells and pharmaceutical compositions comprising host cells, classified in class 536, subclasses 23.5, 24.31, 24.33, class 514, subclass 44 and class 435, subclasses 69.3, 70.1, 320.1 and 372.
- IX. Claims 15 in part, claim 19 (parts 1 and 4) and claims 47, 53, 68, 69, 71, 72, 75, 113 drawn to isolated polypeptides, pharmaceutical compositions, immunogenic fragments, classified, for example, in class 530, subclasses 327 and 806.
- X. Claim 119, drawn to an isolated antibody which binds to a complex of polypeptides encoded by NA Group 1 molecules and an MHC molecule, classified in class 530, subclass .387.7.

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3. The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups VIII, IX and X are structurally and functionally different products which are made by different methods and have different uses. The examination of all groups would require different searches in the U.S. Patent Shoes and the scientific literature and would require the consideration of different patentability issues.

The methods of Groups I-VII differ in the method objectives, method steps and parameters and in the reagents used.

Inventions VIII and I are related as product and process of use. Inventions VIII and V are also related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the nucleic acid of Group I can be used in either method of Group I or V.

Inventions IX and IV are related as product and process of use. Inventions IX and V are also related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case x the polypeptide of Group IX can be used in either method of Group IV or V.

Inventions X and II are related as product and process of use. Inventions X and VII are also related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group X can be used in the method of Group II or VII.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter and because the searches required for the groups are not co-extensive, restriction for examination purposes as indicated is proper.

4. With the election of any Group, a further election of a single SEQ ID NO: 1, 3, 5, 7, 9, 11, 13, 15, 17, 19, or 23 is required. Each polypeptide or nucleic acid encoding said polypeptide is structurally and functionally a different product. The examination of all polypeptides would require different searches in the U.S. Patent Shoes and the scientific literature and would require the consideration of different patentability issues. Because these genes are distinct for the reasons given above and because the searches required for the polypeptides or nucleic acids encoding said polypeptides are not co-extensive, restriction for examination purposes is considered proper.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner

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can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.

Patent Examiner, Group 1642

January 18, 2002


ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600